PATENT
Atty. Docket No.: 13024/35946

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	I hereby certify that this paper is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on this date:
McMichael, J. *et al.*	
Serial No.: 09/495,186	
Filed: February 1, 2000	
For: TREATMENT OF SYMPTOMS OF ASTHMA, ALLERGIES AND OTITIS MEDIA	April 16, 2001
Group Art Unit: 1633	Jeffrey S. Sharp Registration No. 31,879
Examiner: Wilson, M.	Attorney for Applicants

DECLARATION OF HARRY C. GURNEY D.V.M. UNDER 37 C.F.R. §1.132

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

1. I, Harry C. Gurney am a practicing veterinary doctor practicing in Conifer, Colorado and am licensed by the State of Colorado. I received my B.S. in Premedical Studies from the University of Wyoming in 1958 and my D.V.M. from Colorado State University in 1964. Since then I have practiced veterinary medicine on both small and large animals including horses.

2. I submit this declaration to address certain issues raised in the Office Action dated October 18, 2000 in the above-identified application. In particular, I am informed that the Patent Office Examiner has raised questions of whether administration of DNA containing compositions by methods other than by sublingual administration is effective to treat

symptoms of allergies and asthma in subjects suffering from those diseases. In response to those questions, I report that I have used, and am familiar with the use of, the DNA containing compositions of the invention to effectively treat symptoms of allergies in large and small animals and that those compositions were administered by the route of sub-cutaneous injection.

3. I have successfully supervised the use of the DNA containing compositions of the present invention in the treatment of chronic obstructive pulmonary disease (COPD) in a number of small mammals with the case histories set out below.

4. Specifically, a 5 year old female canine presented with COPD, respiratory distress with moist rales (mucoserous), persistent cough with exercise, pulse oximetry revealed reduced oxygen of 81% and increased heart rate, X-rays showed marked bronchial congestion, no significant cardiac dilation. The dog was treated by subcutaneous administration, bid of 0.2 mL of a composition identified to me as "SCTF" that I am informed contained 0.003 mg/mL (0.0006 mg per 0.2 mL dosage) of either salmon or bovine DNA. The subject experienced improved respiration, reduction in rales, pulse-oximetry improved to 89% (90-95% normal) oxygen within 5 days, and reduction in pulse rate. Upon this favorable response, the therapy was discontinued after 3 weeks.

5. A 12 year old female canine presented with COPD, chronic cough due to second hand smoke, pulse oximetry revealed reduced oxygen to 79% with increased pulse rate of 170, X rays revealed significant bronchial fibrosis and congestion (mucoserous), radiographic right side cardiac dilation without significant murmur/auscultation. The subject was treated by subcutaneous administration, bid of 0.2 mL of the SCTF composition. The subject converted to a productive cough which eased both cough and respiration over a period of 2 months and the medication was maintained without recurrence of significant symptoms.

6. A 14 year old female canine presented with COPD and lung mucoserosis secondary to lung cancer. Pulse oximetry revealed a reduced oxygen of 76% with an increased pulse rate to 175 with poor exercise tolerance. This patient was classified as "terminal" due to cancer and an improved quality of life was a primary goal. X-rays demonstrated a generalized

scattering of cancerous nodules throughout the lung fields suggesting metastatic showering from elsewhere in the body. The subject was treated by subcutaneous administration, bid of 0.2 mL of the SCTF composition plus oral keflex antibiotic. Exercise was increased within tolerance levels and the antibiotics discontinued 21 days later. The patient's respiration eased significantly, the pulse oximetry improved to 84% and pulse rate slowed somewhat with an increased tolerance to exercise. This patient ceased coughing except when intentionally stimulated and lived with a significantly improved quality of life with modest spontaneous playful behaviors.

7. An 18 year old female feline presented with COPD and advanced age. This patient presented minimal respiratory difficulties at rest but the combination of notable respiratory compromise and advancing years in age, inactivity, progressive weight loss, and a lack in appetite reduced this patients's quality of life to "just surviving." Pulse oximetry was 85% and the pulse rate was 160 at rest. The subject was treated by subcutaneous administration, bid of 0.2 mL of the SCTF composition and since initiation of treatment advances in age have been uncomplicated, with improved respiration and exercise tolerance along with an owner determined "improved quality of life."

8. An 8 year old female rabbit presented in critical status with COPD of unknown origin which may have been dust induced. Membranes were cyanotic and respiration labored along with increased heart rate on auscultation. The subject was treated by subcutaneous administration, qid of 0.2 mL of the SCTF composition in the hospital for one week and then administered by the owner thereafter. The patient improved significantly within 10 days and the respiratory capacity improved with a concomitant disappearance of cyanosis. While the patient lived only another 14 months, its life during that time was relatively normal and other medications were unnecessary for supportive care. The subject died unexpectedly with the cause of death undetermined but not believed to be due to respiratory causes.

9. A 28 year old horse presented with Heaves (COPD) characterized by a pink, foamy nasal discharge and respiratory distress accompanied by a double expiratory lift. The duration of this recurrent illness and the onset of symptoms was yearly. The horse was treated by subcutaneous administration bid of 0.2 mL of the SCTF composition due to the

severity of symptoms. At the initial examination, the horse had a body temperature of 103°F and penicillin was administered parenterally for 3 days. The urgent respiratory symptoms abated significantly within 48 hours and the antibiotics were discontinued one day later. No other respiratory interventions were performed. The horse continued to improve when the treatment was reduced to bid. Some weeks later, the owner, independently, decided to stop the medication and the horse relapsed into symptoms of respiratory compromise within a week's time. The owner then, independently, restored the bid treatment and the horse improved significantly within 24 hours.

10. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Harry C. Gurney

April 12, 2001